International Conference on Harmonization (ICH)
M2 EWG Meeting - Summary
Brussels, 17 July to 20 July 2000

Participants:

EU: Esteban Gonzalez Juarros, Karel de Neef, Stan van Belkum, M. T. Carrasco Benitez, Thomas Lonngren
EFPIA: Andrew Marr, Stephan Laage, Mervyn Mitchard
PhRMA: Kris Arora, Bob Hizer
FDA: Greg Brolund (Rapporteur), Robert Yetter, William Ridgely
JPMA: Tetsuro Shimokariya, Hitoshi Asano, Harv Martens, Keiji Sawamukai, Masatoshi Ozeki
MHW: Mihoko Okada, Mitsuo Saito,
Observer: Louis Boulay

The tasks accomplished and the decisions agreed are the following:

eCTD

1. The six parties formally voted to accept the following points as an M2 EWG agreement regarding eCTD architecture

- The logical hierarchical structure (content model) of the eCTD is defined by an XML DTD
- Meaning of the term Backbone needs to be defined
- The current version of the eCTD-DTD can accommodate a variety of physical hierarchical structure.
- The Xdossier Internet draft will be evaluated and any applicable part will be inserted in the eCTD specification. Specific documents used in the creation of the eCTD will be acknowledge by informative reference
- A physical hierarchical structure will be built in the DTD. A physical hierarchical structure similar to the Table of Content defined by M4.
- An XML instance of the eCTD-DTD will be part of each submission.

2. Change Control

The change control section of the eCTD Specification document was reviewed and agreed.

3. Work Agreements:
   - Agreed on the outline of a work plan which includes:
     - a means of electronic communication and a document center
     - how to draft the eCTD specification document
     - to work on the eCTD architecture and documentation and a related demonstration
   - Assigned corresponding tasks to regional representatives

4. Co-ordination

   M2 recommended to the Steering Committee that comments regarding the CTD Step 2 document will be made as formal comments from the M2 group. Other questions and clarifications needed from the CTD EWGs will be sent from the M2 rapporteur to the ICH co-ordinators to obtain timely replies from the CTD EWGs.

ICH5 Session Topics

The preliminary ICH5 session topics for M2 are:

Overview of the ICH Common Technical Document – Electronic   15 minutes (Greg Brolund)
Session 3: Regulatory Communications
    M2   (EU, MHW, FDA, HPB, EFPIA, JPMA, PhRMA)
       - E2B/ICSR Implementation   40 Minutes
       - eCTD Architecture and Demonstration   45 Minutes

Joint E2B(M) and M2 EWG Meeting

In a joint meeting was agreed that the M2 will be adequately represented on the E2B(M) EWG at this meeting and at future meetings. The two EWG's agreed that the E2B(M) EWG will make the necessary changes to both the E2B Step 4 document and M2 "Electronic Transmission of Individual Case Safety Reports Message Specification" Step 4 document.

The M2 group voted to exchange test ICSR messages through the ESTRI gateway of each party that has an operating gateway and to document the results including any problems or incompatibilities. A co-ordinator for the test was not identified. During the joint E2B(M) / M2 meeting it was agreed that EFPIA and PhRMA will be asked to co-ordinator for the test of an electronic ICSR in all three regions and that the test may include an evaluation of the consistency of the content of the ICSR message as well as the ability to exchange secure messages electronically.

General

The EWG presented status and results to the ICH Steering Committee. The Steering Committee was asked to approve a meeting of the M2 EWG on October 3,4,5 2000 in Washington D.C. The meeting will be attended by 1 or 2 members from each party. If additional members will attend the meeting, the rapportuer will be notified prior to the meeting.